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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/751,059   | 12/29/2000  | James R. Baker JR.   | UM-04491            | 8985             |
| 23535  | 7590        | 10/19/2006           | EXAMINER            |                  |
| MEDLEN & CARROLL, LLP<br>101 HOWARD STREET<br>SUITE 350<br>SAN FRANCISCO, CA 94105 |             |                      | FUBARA, BLESSING M  |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1618                |                  |

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                       |                         |  |
|------------------------------|---------------------------------------|-------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>                | <b>Applicant(s)</b>     |  |
|                              | 09/751,059                            | BAKER ET AL.            |  |
|                              | <b>Examiner</b><br>Blessing M. Fubara | <b>Art Unit</b><br>1618 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 July 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 186-199 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 186-199 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Examiner acknowledges receipt of amendment and remarks filed 7/25/06. Claims 134-185 are canceled. New claims 186-199 are added and are pending.

### ***Response to Arguments***

Any previous rejections and objections that are not reiterated herein have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 186-199 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for decontaminating an area, (e.g. decontaminating an area by removing or reducing the number of micro-organisms in the area by exposing the area to an oil-in-water emulsion), does not reasonably provide enablement for protecting a surface of a human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This is scope of enablement rejection.

In evaluating the scope of enablement, several factors are to be considered. Note In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)): The factors include: 1) The nature of the

invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

It is noted that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. In re Goodman, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing In re Vaeck, 20 USPQ2d at 1445 (Fed. Cir. 1991).

The courts have stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in patent application. 27 USPQ2d 1662 *Ex parte Maizel*.

### 1) Nature of the invention

The nature of the invention is the contacting of a surface including the surface of a human with an emulsion, and in so doing protect the surface from Herpes Simplex *I* virus.

### 2) State of the prior art

The state of the prior art as it relates to Herpes Simplex *I* virus (HSV1) is that the simplex “virus 1 infect mucous membranes and skin surfaces causing latent infections in the corresponding sensory nerve ganglia. The initial infection may be asymptomatic.” (JAMA, 1999; 282:379-380). Curtis et al. in “herpes simplex virus type 1 and Alzheimer’s disease,” Neurobiology of Aging 20 (1999) 457-465) implicates HSV1 in Alzheimer’s disease.

### 3) The predictability or lack thereof in the art

The method of protection exposes the surface to the instant emulsion of and expects that the surface will be protected from the microorganism. Since the initial infection may be asymptomatic, it is questionable as to when the emulsion is applied to the surface to effect the

protection. The criteria as to who would be exposed is not worked out. There is nothing in the specification that directs the artisan as to the state of the surface regarding infection or lack of infection in the identification of the surface for exposure. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific guidance is required to enable the artisan to practice the full scope of the claimed invention.

In the instant case, the scope of the claimed protection involves protecting the surface of the human from contamination with microorganism without designating when the protection starts and what surface of the human undergoes exposure to the instant emulsion.

4) Amount of direction and guidance present

The direction and guidance provided is limited to BCTP treatment on simulated wound contaminated with *Bacillus cereus* (paragraph [0189]), decontamination and sterilization (paragraph [0208]) and not to what happens to the surface of a human upon exposure of the surface to the instant emulsion. And because, the pharmaceutical art though having high level of skill in the area of infections/contaminations caused by HSV1, decontamination or protection of a surface is still unpredictable. It will require undue experimentation by the artisan to expose any human surface to the instant nanoemulsion and expect a reduction or no contamination from HSV1.

5) The presence or absence of working Examples

There is no working example where any part of the human surface is exposed to the inventive nanoemulsion after identification of contamination/infection by HSV1 or after identification that the human surface is free of the HSV1. There is also no working example where the human surface exposure is monitored for any length of time to measure/determine

either protection from or reduction of HSV1. The working examples is limited to decontamination, bacterial inactivation, and HSV1 inactivation (Table 18). The working examples do not correlate with the scope of the claims.

**6) Breadth of the claims**

The claims are directed to broad protection of any human surface form HSV1. The specification does not inform the public of the limits of the monopoly asserted at the time of filing.

**7) Quantity of experimentation needed**

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would first need to determine how and if human surface is contaminated with HSV1, what part of the human surface is contaminated and determine the extent of the contamination and the duration of the exposure that would produce the desired protection from HSV1 before exposure to the inventive emulsion. This is undue experimentation.

Therefore, in view of the Wands factors, and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of ordinary skill in the art would have to engage in undue experimentation to test and use the scope of the claimed invention encompassed in instant claims, with no assurance of success.

Scope of Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). In view of the quantity of experimentation necessary to determine the parameters listed above, the lack of direction or guidance provided by the specification, the absence of working examples for the demonstration or correlation to the claimed invention, the claimed invention is not

commensurate with the enabling disclosure leading the artisan to engage in undue experimentation.

4. Claims 186-199 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what "surface of a human" means in the context of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Blessing Fubara  
Patent Examiner  
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